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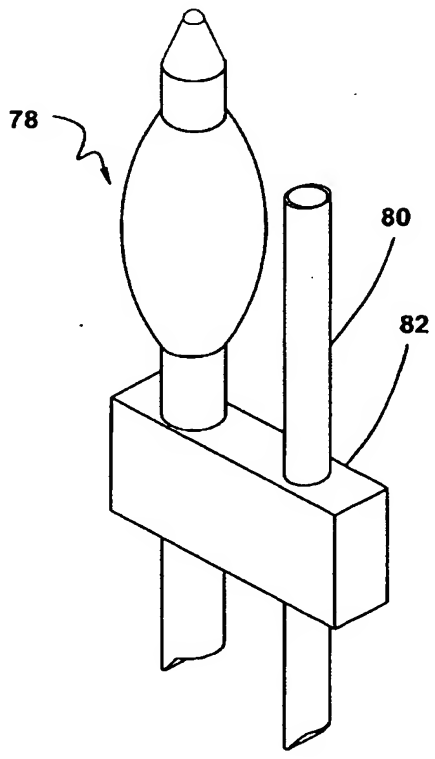
[Continued on next page]

(54) Title: INTRA-AIRWAY VENTILATION



(57) Abstract: A tube for inducing gases into critically ill patients, in which the distal end is perforated, and covered with an inflatable - deflatable sleeve. Gas is pumped into the proximal end of the tube, which inflates the sleeve engaging the inner walls of an airway. The gas, typically a mixture of oxygen, subsequently exits the sleeve and enters the airway. Auxiliary accessories can be attached to the tube.

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SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

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For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

INTRA-AIRWAY VENTILATION

TECHNICAL FIELD OF THE INVENTION

The present invention deals generally with artificial ventilation of the critically ill. More specifically the invention is in the field of intra – tracheal ventilation devices.

BACKGROUND OF THE INVENTION

Artificial ventilation of critically ill, traumatized, or anesthetized persons is a life-saving procedure. Artificial ventilation may be performed by applying negative pressure around the chest with an "Iron Lung", or by pumping gas at positive pressure into the airways, called "Intermittent Positive Pressure Ventilation (IPPV)". IPPV may be applied through a tightly fitting face mask, or via a tube inserted into the trachea of the patient, called "Endotracheal Tube (ETT)". In recent years a hybrid method, namely the "laryngeal mask" - a catheter tip pear shape inflatable occluder that fits over the glottis at the entry to the trachea - has gained popularity. In addition to negative pressure ventilation and IPPV other (alternative) modes of ventilation have been described. These include "High Frequency Ventilation (HFV)", jet ventilation, "Constant Flow Ventilation (CFV)", and external chest vibration with tracheal bias flow.

To achieve effective IPPV, a tight seal must be formed between the gas delivery tube, such as the ETT or a tracheotomy tube, and the patient's airway.

Thus, when gas (air; oxygen) pressure in the delivery tube rises it flows into, and only into, the person's lungs to induce inhalation. When the pressure in the gas delivery system falls bellow the pressure in the lungs the flow is reversed and CO_2 - rich gas exits the lung. In conventional IPPV the expiratory outflow from the lung is through the same lumen of the ETT through which the gas flowed into the lung. Therefore, the lumen of the ETT must be as wide as possible to facilitate free exhalation without build-up of excessive intra-thoracic pressure.

When positive pressure ventilation is used, it is usually possible to control the respiratory rate, the volume of each breath (Tidal Volume) and the relative duration of the inspiratory and expiratory phases of each breath (I:E Ratio). It is also usually possible to control or limit the peak pressure during inspiration (PIP) and the minimal pressure at the end of expiration (PEEP). In addition, it is often desirable to facilitate self-triggering of the initiation of the breathing cycle by sensing the patient's brief drop in airway pressure induced by his/her inspiratory effort. This signal is used to actuate the delivery of a breath by the ventilator in tandem with the patient's own inspiratory effort.

While there are many models of ventilators with a variety of features and controls, all IPPV systems are only capable of ventilating the whole lung en bloc, or, at the most ventilating the two lungs with a special, two lumens ETT, using two ventilators. Current technology does not allow ventilation of lobes or segments of the lung individually, despite the substantial inhomogeneity of the disease processes encountered in most lung diseases.

German Patent 2055049 and US Patent 5,265,593 the contents of which are incorporated herein by reference, disclose an endotracheal tube equipped with a cuff balloon that is connected via an accessory channel to an actuating apparatus that rhythmically inflates the sleeve, while a steady flow of air or oxygen is blown through the main lumen of the tube. When the cuff baloon is inflated inside the patient's trachea it occludes the exit of air around the tube and the lungs inflates. When the cuff balloon is deflated, the lungs deflate with gas exiting around the tube, while gas is still flowing into the trachea through the tube's main channel. The lack of control over intra thoracic pressure leading to risk of lung hyperinflation and pneumothorax are major concerns with this method. The invention disclosed herewith describes an improved intra-tracheal ventilation method and tube that overcomes the deficiencies of the previous method.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a schematic isometric description of a distal part of a tube of the invention;

Fig. 2 is a schematic cross sectional view of a distal part of a tube of the invention in which the sleeve attached is inflated;

Fig. 3A is a schematic isometric view of a inflated sleeve over the distal side of a tube of the invention;

Fig 3B is a schematic cross sectional view in a tube sleeve combination;

Fig. 3C is a schematic cross sectional view in a tube sleeve combination;

Fig. 3D is a schematic cross sectional view in a tube sleeve combination;

Fig. 4 is a schematic isometric view of a distal end of a sleeved tube inserted into an airway;

Fig. 5 is a schematic isometric view of an accessory tube in combination with the standard tube of the invention;

Fig. 6A is a schematic isometric view of a stabilizing spring at the distal side of the tube of the invention in a contracted position;

Fig. 6B is a schematic isometric view of a stabilizing spring at the distal side of the tube of the invention in a released position.

DETAILED DESCRIPTION OF THE PRESENT INVENTION

In accordance with the present invention, an intra-tracheal ventilation apparatus consists of a thin tube whose distal end is inserted into the patient's trachea. The distal end of the tube is surrounded by an inflatable/deflatable elastic sleeve (cuff balloon) whose inner volume is connected to the lumen of the tube via one or a plurality of perforations in the wall of the tube. In **Fig. 1** to which reference is now made, A distal end **20** (the side inserted in the body) of a tube of the invention is shown isometrically. The tube is perorated with holes such as hole **22**. The lumen **24** of the tube is shut off by tip **26** but the perforations facilitate a direct connection between the lumen and the external volume. The perforated zone is covered completely by an inflatable sleeve attached to the tube by an air – tight (hermetic) binding at both extremities zone. The proximal end of the tube is connected to an intermittent gas delivery system that blows pulses of compressed gas at a specified flow rate and frequency into the lumen of the tube. When gas such as air or an oxygen mixture is blown into the tube, sleeve first inflates and expands to a volume that is sufficient to occlude the airway in which it resides. This is better explained with reference to **Fig. 2**. Air or another combination of oxygen is pumped through the lumen of the tube **30** in the direction of arrow **32** to be subsequently excluded through perforations **34** into the lumen of the inflated sleeve **36**, and from there to the ambient volume. In a typical case the ambient volume is the lumen of a tracheal element. The gas exits the sleeve through perforations such as

perforations **38** in the distal side. In an inflated state the sleeve may take the form of a sphere as in **Fig. 3A** to which reference is now made, or other forms to better fit and subsequently block the inner surface of the airway. In **Figs. 3B – D** cross sections in some other forms of sleeves are shown schematically in a inflated state. In **Fig. 3B** the sleeve is tapered at the front. In **Fig. 3C** the sleeve is constricted at the middle, and in **Fig. 3D** the sleeve is tapered at the front and back parts. In each case the arrows denote the general area in which the perforations are situated. The sleeve attached to the tube is extendable and retractable, facilitating reversible air – tight locking of airways in the human or animal body. Variations in the sleeves are provided to accommodate for a variable number of perforations in the sleeve and the extent and form of blocking area abutting the inner walls of the airway. Thus different sleeves are provided, of different sizes (circumference and length) to best fit the airways of certain individuals. The sleeves are made by using specific mold forms, or by incorporating a fine mesh of non-stretchable fibers at the desired shape in the balloon's wall material.

In **Fig. 4** to which reference is now made, a schematic description of an insertion of a tube tip with deflated sleeve **60**, which is pushed in the direction of arrow **62** towards the lumen of an airway **64**.

As a functional example, the tip of the tube of the invention is introduced into an airway in the lung and as gas is blown into the tube, it exits through its perforations, filling the lumen of the sleeve. As the sleeve extends, it lock to the walls of the airway, permitting flow through the perforations in the front (distal side) of the sleeve. This gas can now inflate the lung or lung portions whose

main airway is occluded by the inflated balloon. When gas pumping diminishes, at the end of each pulse, the pressure inside the tube's lumen immediately falls and the inflated sleeve deflates through the hole. As the sleeve deflates it loosens its grip on the internal walls of the blocked airway, allowing for exhaled gas to exit the lungs or lung portion. In accordance with preferred embodiment of the invention the deflation of the sleeve is induced by the elastic recoil of the sleeve, constructed from an elastomer thin membrane such as silicone that can expand and relax thousands of times without changing its elastic properties. Alternatively, applying suction (negative pressure) to the tube collapses the sleeve or enhances the collapse.

In some embodiments, a portion of the distal tip of the tube is removed, to be replaced by a diffuser, allowing flow of some of the gas by passing the pores in the diffuser, whereas the rest of the flowing gas passes through the perforations in the walls of the tube and sleeve, respectively.

In yet another embodiment, the sleeve wall is not perforated tube is open, either directly or with a diffuser, allowing all the gas to flow into the while the tip of the lumen of the airway in which it is lodged after expanding the sleeve by passing a small amount of gas into the sleeve through the holes in the tube wall beneath the sleeve. In this embodiment, the sleeve deflates through the same connecting holes in the tube wall. This occurs when the pressure inside the tube drops at the end of the inspiratory gas delivery pulse.

Pressure sensing

Adding a pressure-sensing element at the distal side of the tube to sense the intra-airway pressure throughout the ventilation may be advantageous. Such a pressure sensing may be achieved by a pressure transducer (e.g. Milar® catheter-tip transducer), or by passing a narrow pressure-sensing catheter through the length of the tube with a forward directed opening. The information on the intra-airway pressure may be monitored continuously. The information on the pressure at any time during the ventilation may be used to prevent excessive intra-airway pressure build-up, beyond a pre-set value, such as 30 cm H_2O. The information about the pressure may also be used to determine and control the desired peak inspiratory pressure (PIP) during each breath and the desired positive end expiratory pressure (PEEP). The pressure tracking at the distal end of the tube may also be used to trigger a pulse of gas flow (a breath) when the level of pressure transiently drops due to the patient's own inspiratory effort. In addition to the pressure sensor, a gas composition sensor may be employed as well, to alert of undesirable component or component ratio in the gas composition at the surrounding volume.

Accessories to the tube

In **Fig. 5** to which reference is now made shows a sleeve **78** and a tube of the invention, aligned and secured with an accessory tube **80**, typically a catheter, in parallel by a clamp **82**. The clasp may optionally allow a sliding movement of

the accessory tube along the length of the clamp. This allows variable positioning of the orifice of the accessory tube with respect to the sleeve and tip. A secondary catheter or probe may be used to extract secretions from the airways by suction, lavage the lung, insert medications. Tubes or other cylindrical element may be use in the accessory position, in addition to catheters. Very useful examples are observation means for the airways using a fiber-optic scope or a miniature video camera, or obtaining samples of the airway tissue and lining by brushing or with a biopsy tool.

Another feature of the device of the invention is a proximal side-port with an appropriate connector such as a Luer lock with a one-way valve that allows injection of agents such as liquids or gases or aerosols into the gas stream flowing into the patient's airways. These liquids may contain medications, such as adrenaline or atropine.

Additional accessories at the tip of the tube or at the tip of an auxiliary tube may be a microphone or a video camera which constitute optional gatherers of information for monitoring the welfare of the patient or the progress of insertion of the tube inside the patient.

Tube stabilizing and insertion limiters

Additionally we disclose a method to prevent insertion of the tube too far into the airways, thereby avoiding the risk of wedging the tube in an airway. This is achieved by equipping the tip of the tube with a hinged ring of a diameter matching the narrowest airway in which the tip of tube is to be lodged. The ring prevents the catheter from being advanced too far into the

lung. The ring may be made from a rigid material such as bio-compatible metal or plastics. Alternatively, the ring may be made from an inflatable narrow tube connected via a secondary channel to an external inflating device such as a syringe. Alternatively, as described schematically in **Figs 6A – 6B** to which reference is now made, a contracted spring **90** as in **Fig. 6A** may be released as in **Fig. 6B** for adhering to the inner walls of the airway. The spring may be concealed by a retractable thin-wall sleeve during the insertion of the tube into the trachea. Once inside the trachea, the sheet may be retracted by pulling it back, allowing the pre-stressed coiled element to spring out and attain its unstressed shape and dimensions inside the airways. The same method be useful to stabilize the tip of the tube and keep it about the centre of the airway.

Special uses of the invention

Under certain circumstances it is important to selectively ventilate different lung regions. This is particularly desirable when the lung disease is highly non-homogenous. The device may be used for such application. This is achieved by inserting a plurality of tubes selectively into main-stem or lobar bronchi. These tubes are narrower and have smaller sleeves than the standard ones, but are otherwise similar in construction and function. The tubes may be positioned using a fiber-optic or video camera scope that can be maneuvered to specific sites in the airways. Additionally, certain lung regions may be inflated to higher pressures while others are kept at low inflation pressure. It is possible using the device of the invention to apply one

or more intra-airway ventilation catheters by passing them through a standard tube for combined selective and global ventilation of the lung.

CLAIMS

1. A tube for introducing gases into critically ill patients comprising:
   - a perforated zone at or near the distal end of said tube, and
   - an inflatable/deflatable sleeve covering said perforated zone of said tube allowing direct connection between the lumen of said tube and the lumen of said sleeve, wherein said sleeve is hermetically bound peripherally at its two extremities to said tube, allowing flow of gas from the lumen of said tube to an airway in which the tube tip is inserted.

2. A tube for inducing gases into critically ill patients as in claim 1 and wherein the distal orifice of said tube is sealed.

3. A tube for inducing gases into critically ill patients as in claim 1 and wherein the distal orifice of said tube is perforated.

4. A tube for inducing gases into critically ill patients as in claim 1 wherein a clamp holds said tube substantially in parallel with a cylindrical accessory.

5. A tube for inducing gases into critically ill patients as in claim 4 and wherein said cylindrical accessory is slidable with respect to said clamp. .

6. A tube for introducing gases into critically ill patients as in claim 1 wherein at least one side port is disposed along said tube for introducing agents into said gases.

7. A tube for inducing gases into critically ill patients as in claim 1 wherein at least one sensor is disposed at substantially the distal end of said tube.

8. A tube for inducing gases into critically ill patients as in claim 7 and wherein said at least one sensor is a microphone.

9. A tube for inducing gases into critically ill patients as in claim 7 and wherein said at least one sensor is a camera.

10. A method for introducing gas into the airways of a patient comprising the steps of:

- introducing a distal portion of a tube into said patient airways;
- inflating said tube by pressurizing gas in said tube from a proximal end of said tube;
- introducing gas into said sleeve through perforations in said tube;
- inflating said sleeve into a blocking position of said airway;
- introducing gas into said airway through said tube, and
- deflating said sleeve for allowing gas to flow out of said airway.

11. A method for introducing gas into the airways of a patient as in claim 10 wherein said distal portion of said tube is insertion limited.

12. A method for introducing gas into the airways of a patient as in claim 10 and wherein the progress of said insertion is monitored.

13. A method for introducing gas into the airways of a patient as in claim 10 and wherein the air pressure at the airway is monitored.

14. A method for introducing gas into the airways of a patient as in claim 13 and wherein the progress of said insertion is continuously monitored.

15. A tube for inducing gases into critically ill patients as in claim 7 and wherein said at least one sensor is a pressure transducer.

16. A tube for inducing gases into critically ill patients as in claim 7 and wherein said at least one sensor is a gas composition sensor.

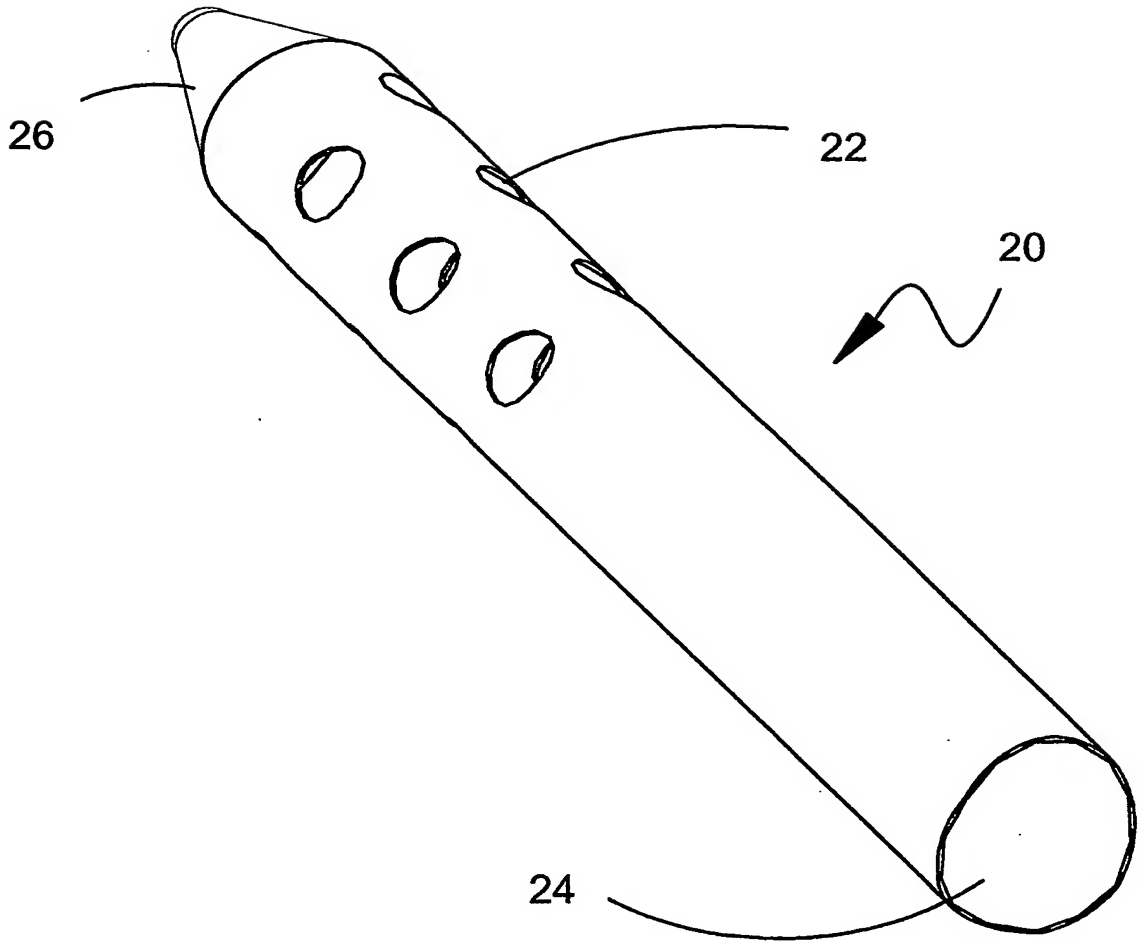

Fig. 1

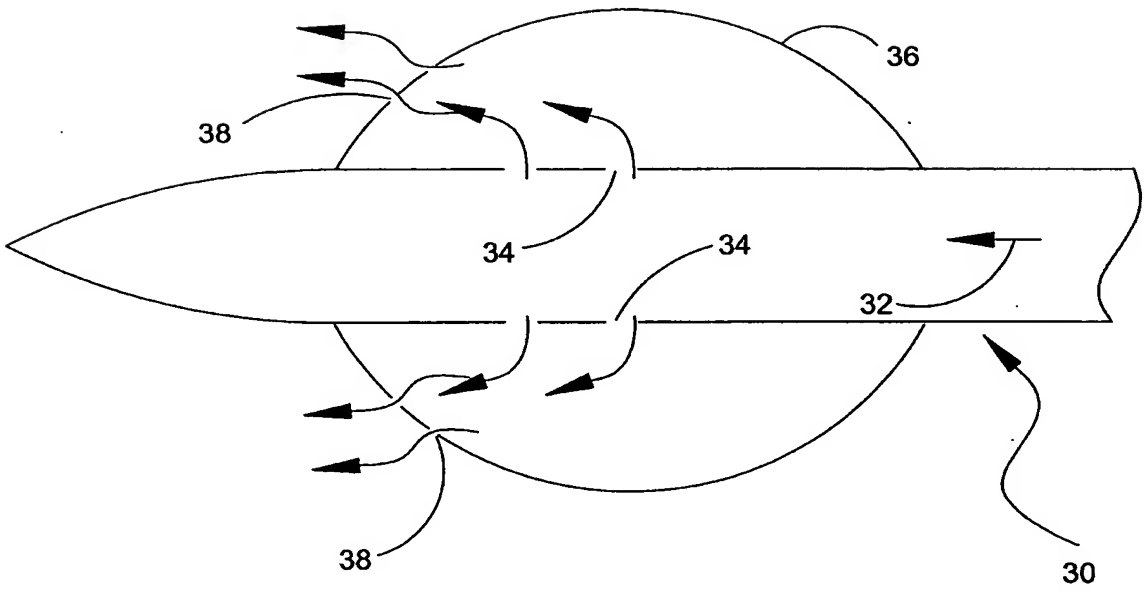

Fig. 2

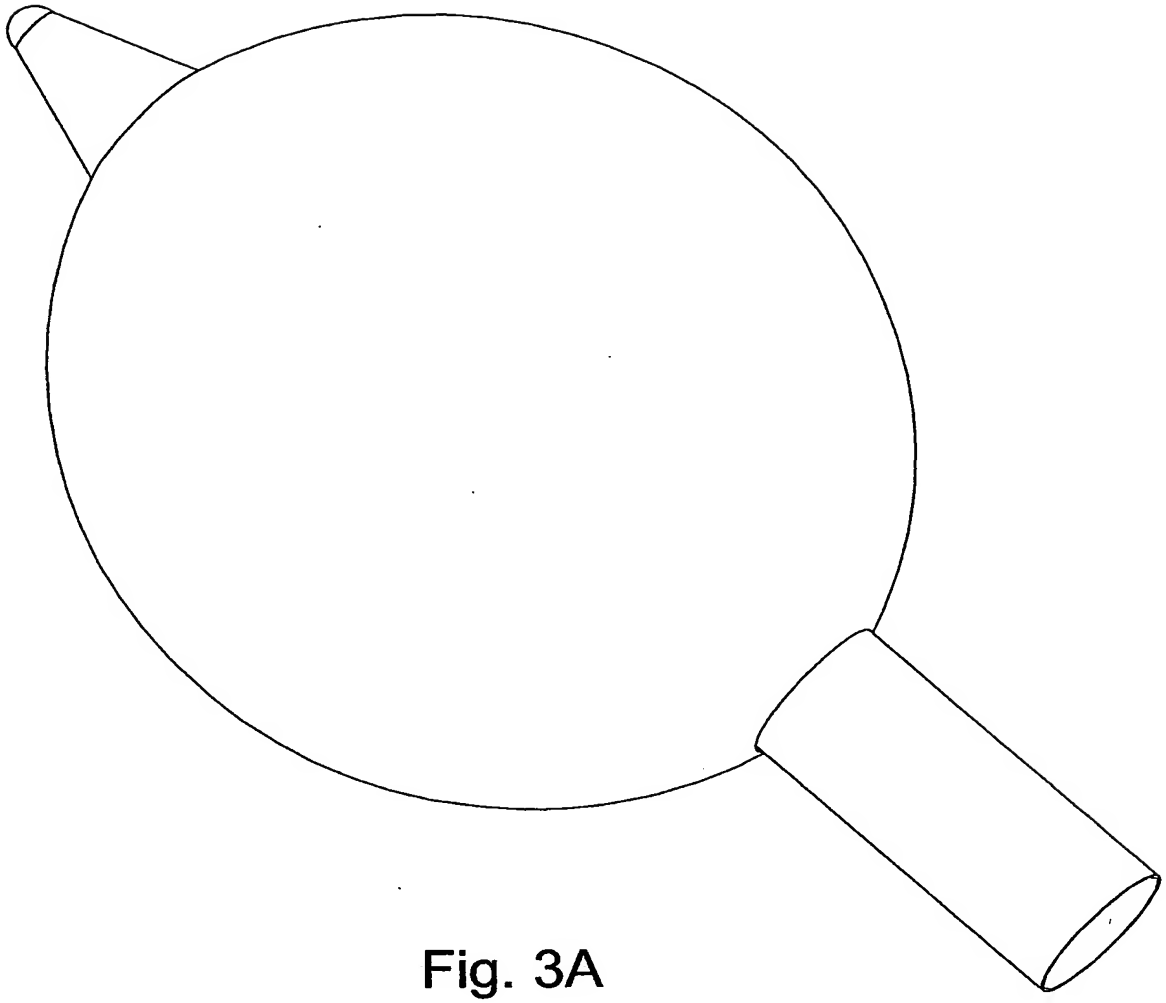

Fig. 3A

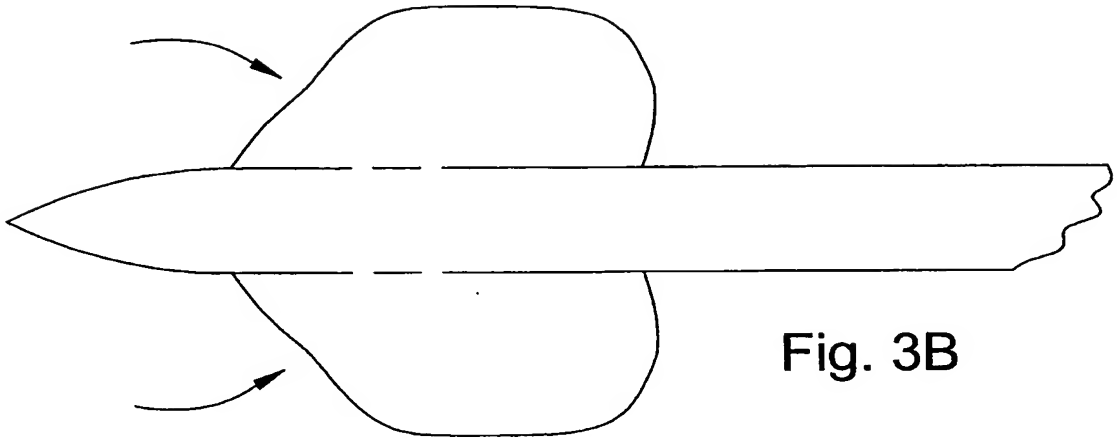

Fig. 3B

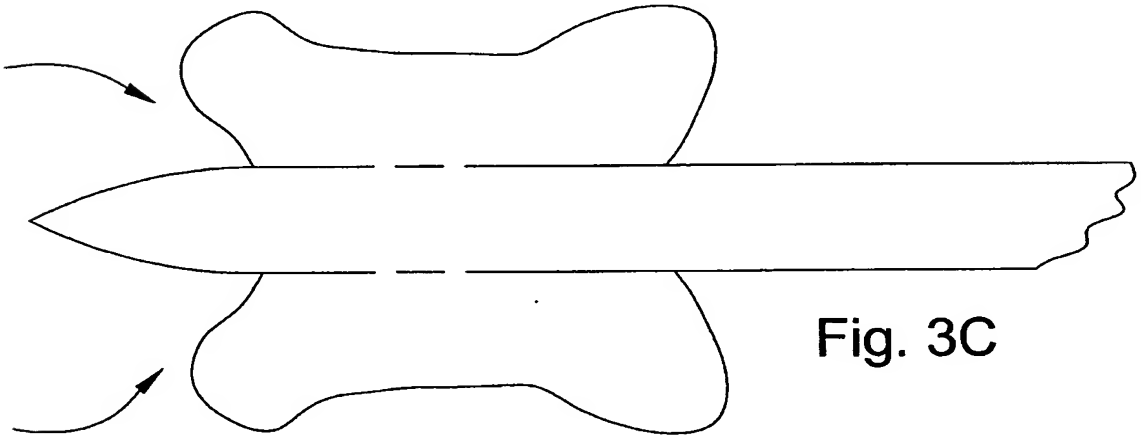

Fig. 3C

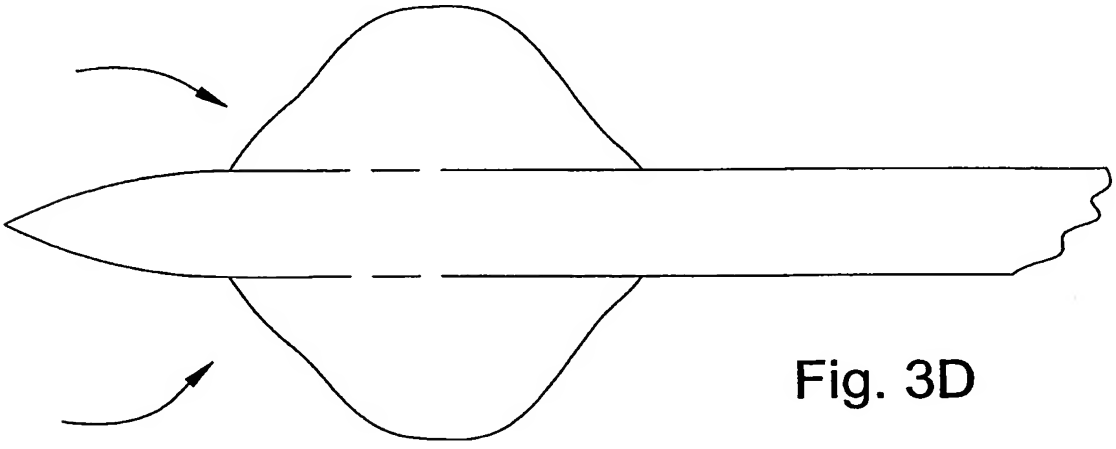

Fig. 3D

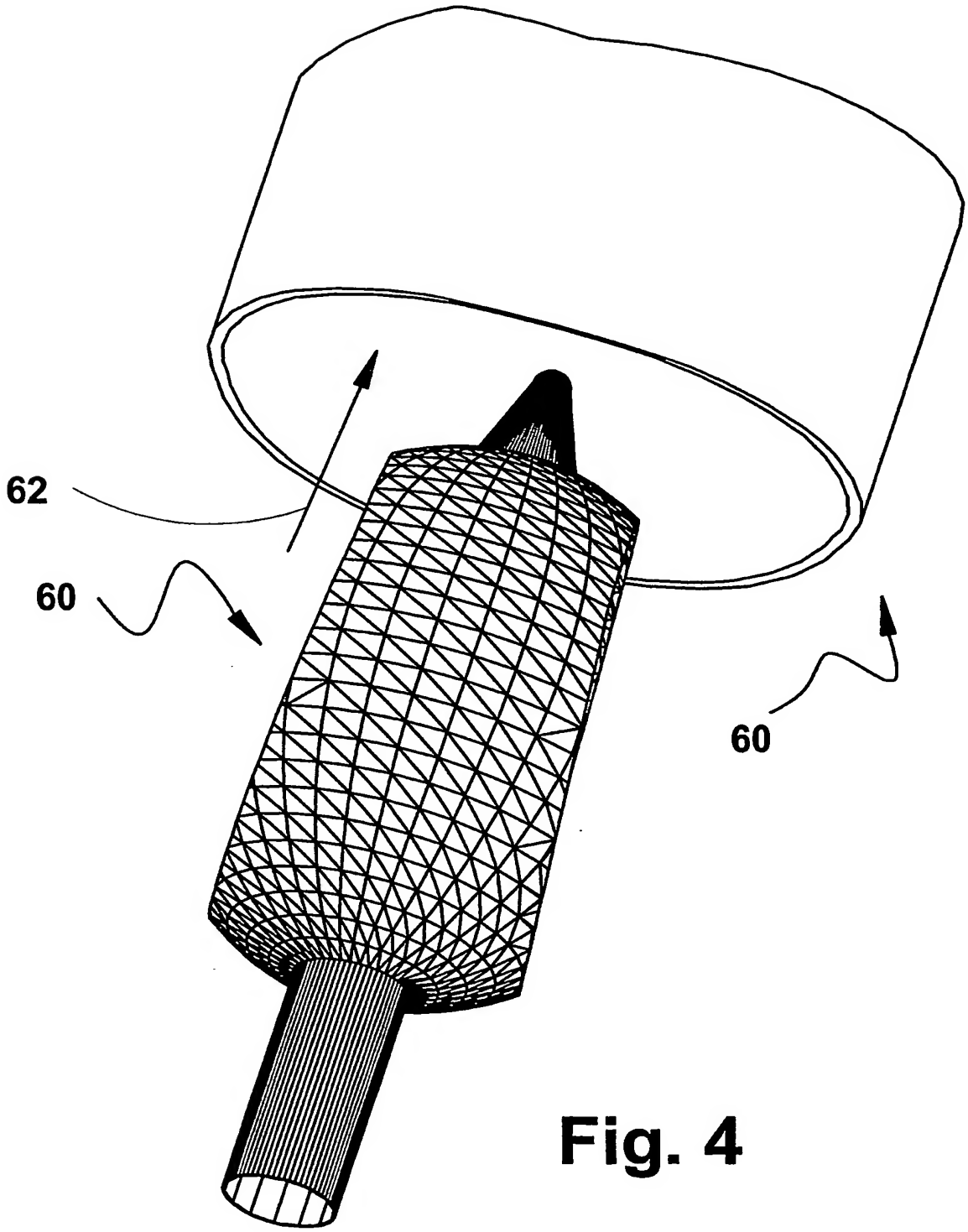

Fig. 4

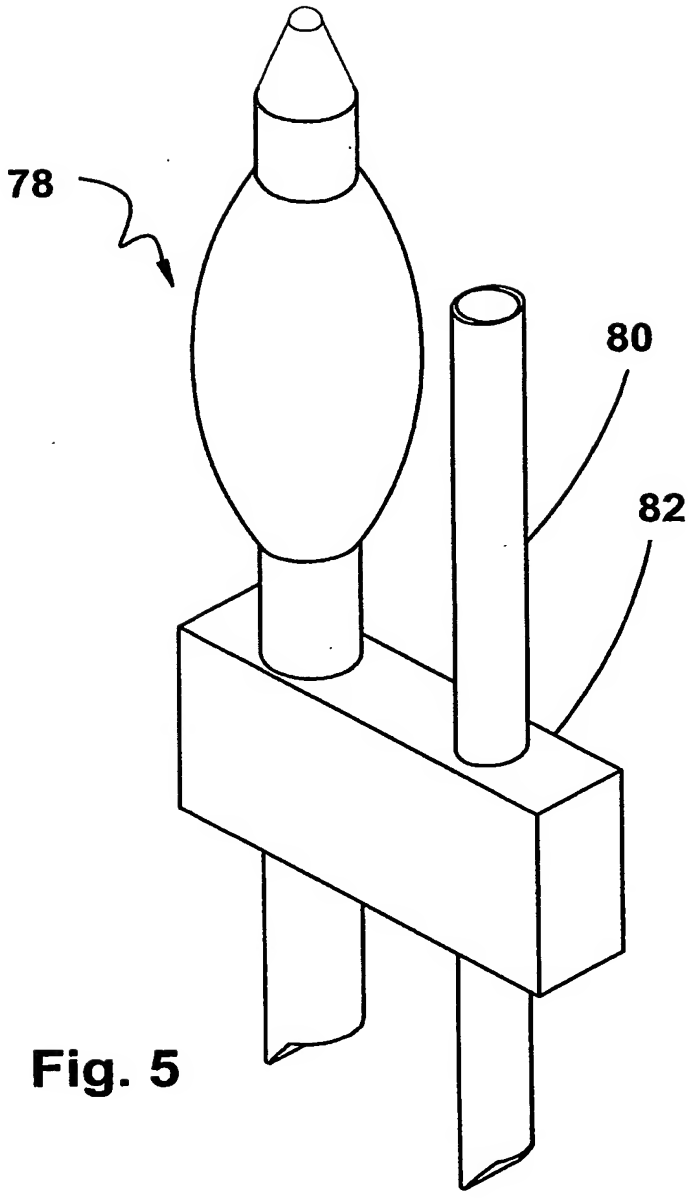

Fig. 5

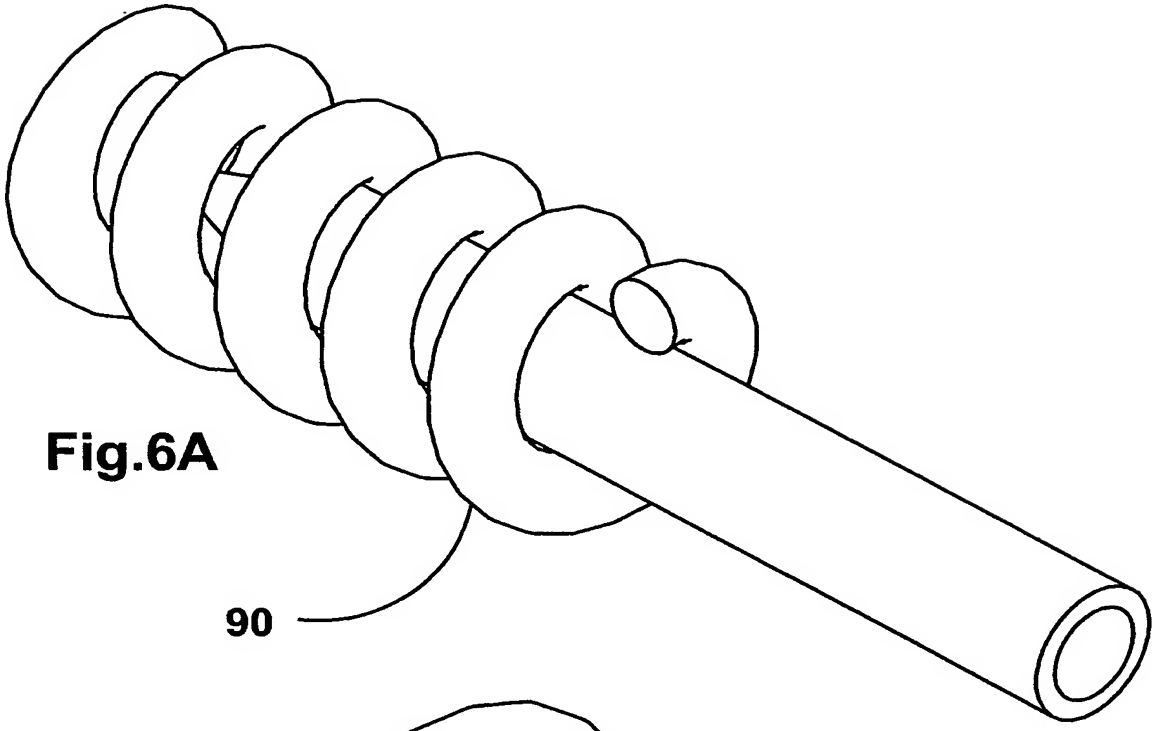

Fig.6A

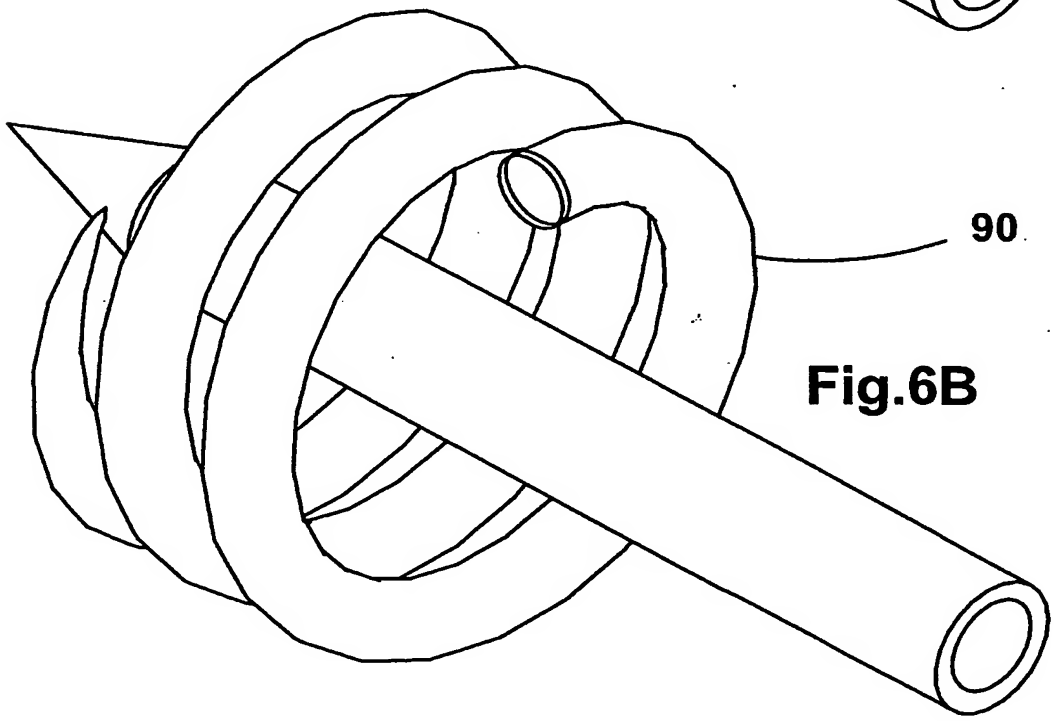

Fig.6B

INTERNATIONAL SEARCH REPORT

Intern[illegible]lication No
PCT/IL 03/00939

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61M16/04 A61F2/20

נתקבל

According to International Patent Classification (IPC) or to both national classification and IPC

11 08. 2004

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61M A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	GB 1 153 863 A (HILTON CECIL LEWINSOHN) 29 May 1969 (1969-05-29)	1
Y	page 1, line 47 - line 88; figure 1	2

X	US 3 481 339 A (PUIG JORGE ALBERTO MILLET) 2 December 1969 (1969-12-02) column 4, line 28 - column 5, line 12; figure 1 column 6, line 5 - line 16	1

Y	US 4 335 723 A (PATEL BHUPENDRA C) 22 June 1982 (1982-06-22) column 4, line 35 - line 45; figure 1	2

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
25 March 2004	29 JUN 2004

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Zeinstra, H

Form PCT/ISA/210 (second sheet) (January 2004)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IL 03/00939

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 10-14
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [X] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

1,2

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box I.1

Claims Nos.: 10-14

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1,2

   Tube for introducing gases into critically ill patient comprising a sealed distal orifice.
   (Problem: During insertion of the tube in the trachea, it happens that mucous parts enter and block the lumen of the tube).

   ---

2. claims: 1,3

   Tube for introducing gases into critically ill patient comprising a perforated distal orifice.
   (Problem: gas leakage during ventilation of the patient)

   ---

3. claims: 1,4,5

   Tube for introducing gases into critically ill patient comprising a clamp.
   (Problem: it is difficult to track and hold the positionning of the distal end of the tube in the lung)

   ---

4. claims: 1,6

   Tube for introducing gases into critically ill patient comprising a side port.
   (Problem: it is difficult to introduce medication to the patient whitout disconnecting the ventilation of the patient)

   ---

5. claims: 1,7-9,15,16

   Tube for introducing gases into critically ill patient comprising a sensor at the distal end.
   (Problem: the introduction of the tube in the lung is difficult)

INTERNATIONAL SEARCH REPORT

Information on patent family members

Intern[illegible]plication No
PCT/IL 03/00939

Patent document cited in search report		Publication date	Patent family member(s)		Publication date
GB 1153863	A	29-05-1969	NONE		
US 3481339	A	02-12-1969	DE	1766155 A1	03-06-1971
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			GB	1171439 A	19-11-1969
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